

# NCI SBIR Contracts Funding Webinar

***October 30, 2013 3 – 4:30 pm EDT***

**For audio, dial in: 240.276.6338  
Meeting ID: 735 583 026**

For Technical Support, call **866-229-3239** and choose **option 1**



# Agenda



|                                                                                                                    |                |
|--------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Welcome</b><br><b>Jennifer Shieh</b>                                                                            | <b>3:00 pm</b> |
| <i>Overview of the NCI SBIR/STTR Programs</i><br>Michael Weingarten                                                | 3:05 pm        |
| <i>What Does It Take to Get Awarded?</i><br><i>Tips on Submitting a Proposal</i><br>Michael Weingarten             | 3:15 pm        |
| <i>The Contracts Process at NCI:</i><br><i>How are SBIR Contracts Different from Grants?</i><br>Michael Weingarten | 3:30 pm        |
| Q&A                                                                                                                | 3:40 pm        |
| <i>FY2014 Contract Funding Opportunities at NCI</i><br>Andrew Kurtz and Deepa Narayanan                            | 3:50 pm        |
| More Q&A                                                                                                           | 4:10 pm        |
| Closing Remarks                                                                                                    | 4:25 pm        |

## **Contract Topic Details:**

**<http://sbir.cancer.gov/funding/contracts>**

**EXTENDED**

**Proposal Deadline:**

**November 25, 2013 at 4:30PM Eastern Time**

**Amendment published 10/25/13**

**<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-013.html>**

# Submit Your Questions

Submit your questions any time via the Q&A box on the right-hand side of your screen.

If you do not see the Q&A box, you can expand it by hovering over the **green bar** at the top of your screen and clicking the Q&A button.



# Submit Your Questions



Please submit questions of a general nature, with no proprietary information.

We will not answer questions specific to your project in this webinar. Send your questions about:

**CONTRACTS** to Elizabeth Shanahan,  
[eshanahan@mail.nih.gov](mailto:eshanahan@mail.nih.gov) or

**GRANTS** to [NCIsbir@mail.nih.gov](mailto:NCIsbir@mail.nih.gov)

The webinar slides, audio recording, and Q&A will be published to the website, <http://sbir.cancer.gov>

# Agenda



|                                                                                                              |                |
|--------------------------------------------------------------------------------------------------------------|----------------|
| Welcome<br>Jennifer Shieh                                                                                    | 3:00 pm        |
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# Congressionally-Mandated Programs



Set Aside  
(FY14)

## Small Business Innovation Research (SBIR)

Set-aside program for small business concerns to engage in Federal R&D with the potential for commercialization

*Federal agencies with an extramural R&D budget > \$100M*

**2.8%**

## Small Business Technology Transfer (STTR)

Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions with the potential for commercialization

*Federal agencies with an extramural R&D budget > \$1B*

**0.40%**

**~\$700M annually at NIH**  
**~\$110M annually at NCI**

# Reasons to Seek SBIR/STTR Funding



- Provides seed funding for innovative technology development

## Not a Loan

No repayment is required

Doesn't impact stock or shares in any way (i.e., non-dilutive)

- Intellectual property rights retained by the small business
- Provides recognition, verification, and visibility
- Helps provide leverage in attracting additional funding or support (e.g., venture capital, strategic partner)

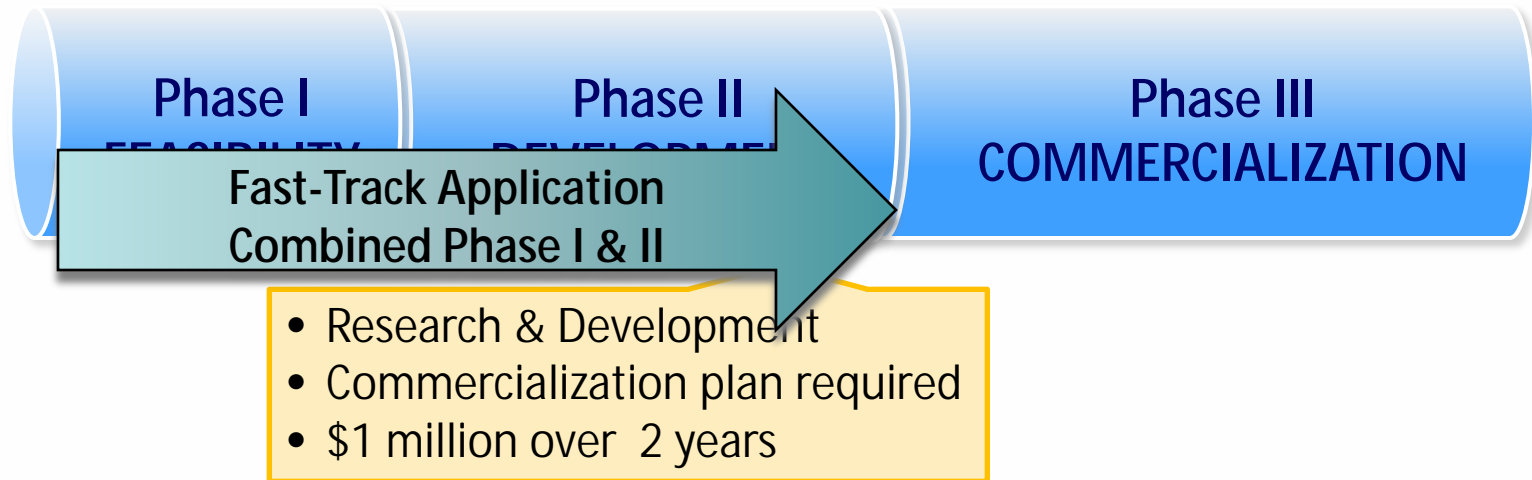


# SBIR & STTR: Three-Phase Program



- Proof-of-Concept study
- \$150,000 over 6 months (SBIR) or 1 year (STTR)

- Commercialization stage
- Use of non-SBIR/STTR funds



\* Hard caps on award sizes: \$225,000 for Phase I; \$1.5 million for Phase II

Note: Actual funding levels may vary by topic.

# NCI SBIR Phase IIB Bridge Award



Phase I  
FEASIBILITY

Phase II  
DEVELOPMENT

NCI SBIR Phase IIB Bridge Award

CROSSING THE VALLEY OF DEATH

Phase III  
COMMERCIALIZATION

- Provides up to \$1M per year for up to 3 years
- Open to any NIH-funded Phase II awardees with projects relevant to NCI mission
- Accelerates commercialization by incentivizing partnerships with third-party investors & strategic partners earlier in the development process
- Competitive preference and funding priority to applicants that can raise substantial third-party funds (i.e.,  $\geq 1:1$  match)

# SBIR Eligibility Requirements

*New Rules starting 1/28/13*



- Applicant is a Small Business Concern (SBC)
  - Organized for-profit U.S. business
  - 500 or fewer employees, including affiliates
  - PI's primary employment (>50%) must be with the SBC at time of award & for duration of project
  - **> 50% U.S.- owned by individuals** and independently operated\*
- OR**
- **> 50% owned and controlled by other business concern/s that is/are  
> 50% owned and controlled by one or more individuals\***
- OR**
- **> 50% owned by multiple venture capital** operating companies, hedge funds, private equity firms, or any combination of these \*

\*Formerly  $\geq 51\%$ ; \*New rule starting 1/28/13, NIH SBIR only

Ask questions any time using the Q&A box

# STTR Eligibility Requirements



- **Applicant is a Small Business Concern (SBC)**
- **Organized for-profit U.S. business**
- **Formal cooperative R&D effort**
  - Minimum 40% by small business
  - Minimum 30% by US research institution
- **US Research Institution: college or university; non-profit research organization; Federally-Funded R&D Center (FFRDC)**
- **Principal Investigator's primary employment may be with either the SBC or the research institution**
- **SBC must have right to IP to carry out follow-on R&D and commercialization**

# SBIR vs. STTR: Which Program is Best for You?



## SBIR

## STTR

### Research Partner

Permits partnering  
*Small business must do  
67% Phase I, 50% Phase II*

**Requires** partnering with  
US research institution  
*Small business min. 40%,  
Research institution min. 30%*

### Principal Investigator

Primary employment **must** be  
with small business

PI may be employed by either  
small business or research  
institution, and must commit  
minimum of 10% effort to project

Small Business Concern is **ALWAYS**  
Applicant/Awardee Organization

# The NIH SBIR/STTR Programs

<http://sbir.nih.gov>



Ask questions any time using the Q&A box

# NIH = 27 Institutes & Centers

## 24 Participants in the SBIR/STTR Program



Office of Research  
Infrastructure Programs  
(ORIP)

The Office of the Director (OD)

National Institute  
on Aging  
(NIA)

National Institute  
on Alcohol Abuse  
& Alcoholism  
(NIAAA)

National Institute  
of Allergy &  
Infectious Diseases  
(NIAID)

National Institute  
of Arthritis &  
Musculoskeletal &  
Skin Diseases (NIAMS)

National Cancer  
Institute (NCI)

National Institute  
of Child Health &  
Human Development  
(NICHD)

National Institute on  
Deafness & Other  
Communication  
Disorders (NIDCD)

National Institute  
of Dental and  
Craniofacial  
Research (NIDCR)

National Institute  
of Diabetes &  
Digestive & Kidney  
Diseases (NIDDK)

National Institute  
on Drug Abuse  
(NIDA)

National Institute  
of Environmental  
Health Sciences  
(NIEHS)

National Eye  
Institute  
(NEI)

National Institute  
of General  
Medical Sciences  
(NIGMS)

National Heart,  
Lung, & Blood  
Institute (NHLBI)

National Human  
Genome Research  
Institute (NHGRI)

National Institute  
of Mental Health  
(NIMH)

National Institute  
of Neurological  
Disorders &  
Stroke (NINDS)

National Institute  
of Nursing Research  
(NINR)

National Institute on  
Minority Health &  
Health Disparities  
(NIMHD)

National Center  
for Complementary  
& Alternative  
Medicine (NCCAM)

Fogarty  
International  
Center (FIC)

National Center  
for Advancing  
Translational Sciences  
(NCATS)

National Library  
of Medicine (NLM)

National Institute  
of Biomedical  
Imaging &  
Bioengineering (NIBIB)

NIH Clinical  
Center (CC)

Center for Information  
Technology (CIT)

Center for Scientific  
Review (CSR)

← No funding  
authority



# Multiple Funding Solicitations

*Know the Application Deadlines*



## **SBIR & STTR Omnibus Solicitations for Grant Applications**

*Release:* January

*Receipt Dates:* April 5, August 5, and December 5

**See the NIH Guide for other Program Announcements (PA's)  
and Requests for Application (RFA's), i.e. grants**

*Release:* Weekly

*Receipt Dates:* Various

## **Solicitation of the NIH & CDC for SBIR Contract Proposals**

*Release:* August – *sign up for the email list to get notified!*

*Receipt Date:* **November 25**

**<http://grants.nih.gov/grants/guide>**



# <http://sbir.cancer.gov>

 National Cancer Institute

U.S. National Institutes of Health | [www.cancer.gov](http://www.cancer.gov)

 **SBIR & STTR**

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Leading small business innovation and commercialization in the fight against cancer

### What are the NCI SBIR & STTR Programs?

The goal of the NCI is to eliminate the suffering and death due to cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are NCI's engine of innovation for developing and commercializing novel technologies and products to prevent, diagnose, and treat cancer.

The SBIR & STTR Programs are one of the largest sources of early-stage technology financing in the United States. We welcome entrepreneurs and small business leaders to this website to explore grant and contract funding opportunities and a new spirit of collaboration with the NCI.

[\[Learn More\]](#)

### Sign up for Updates

Sign up to receive updates and news about the NCI SBIR & STTR Programs and upcoming funding opportunities.

### Latest Announcements

**[SBIR Program FY 2011 Contract Funding Available](#)**

The FY 2011 NCI solicitation for SBIR contract proposals has been issued:  
[PHS 2011-1, Solicitation for SBIR Contract Proposals](#)

**Receipt Date: November 8, 2010**



**Register Today**   
**2010 NCI SBIR Investor Forum**  
November 9 | Stanford, CA

The NCI SBIR will host its second Investor Forum designed to connect the strongest and most promising NCI SBIR funded companies with life science

# The NCI SBIR Development Center

<http://sbir.cancer.gov>

A collage of four images: a scientist in a lab coat and safety glasses holding a flask with red liquid; two people shaking hands; a person holding a large multi-well plate with orange liquid; and a person looking at a laptop screen.

Ask questions any time using the Q&A box

# NCI SBIR Development Center Program Directors



**Michael Weingarten, MA**  
*Director*  
NCI SBIR Development Center



**Greg Evans, PhD**  
*Lead Program Director*  
Cancer Biology, E-Health, Epidemiology, Research Tools



**Patricia Weber, DrPH**  
*Program Director*  
Digital Health, Therapeutics, Biologics, SBIR Investor Forum, FRAC Workshop



**Deepa Narayanan, MS**  
*Program Director*  
Cancer Imaging, Clinical Trials, Radiation Therapy, SBIR Investor Forum, FRAC Workshop



**Ming Zhao, PhD**  
*Program Director*  
Cancer Diagnostics & Therapeutics, Cancer Control & Prevention, Molecular Imaging, Bioinformatics, Stem Cells



**Andrew J. Kurtz, PhD**  
*Lead Program Director*  
Biologics, Small Molecules, Nanotherapeutics, Molecular Diagnostics, Bridge Award



**Jian Lou, PhD**  
*Program Director*  
In-Vitro Diagnostics, Theranostics, early-stage drug development, Bioinformatics, FRAC Workshop



**Todd Haim, PhD**  
*Program Director*  
Small Molecules, Biologics, Immunotherapeutics, Theranostics, SBIR Investor Forum, FRAC Workshop

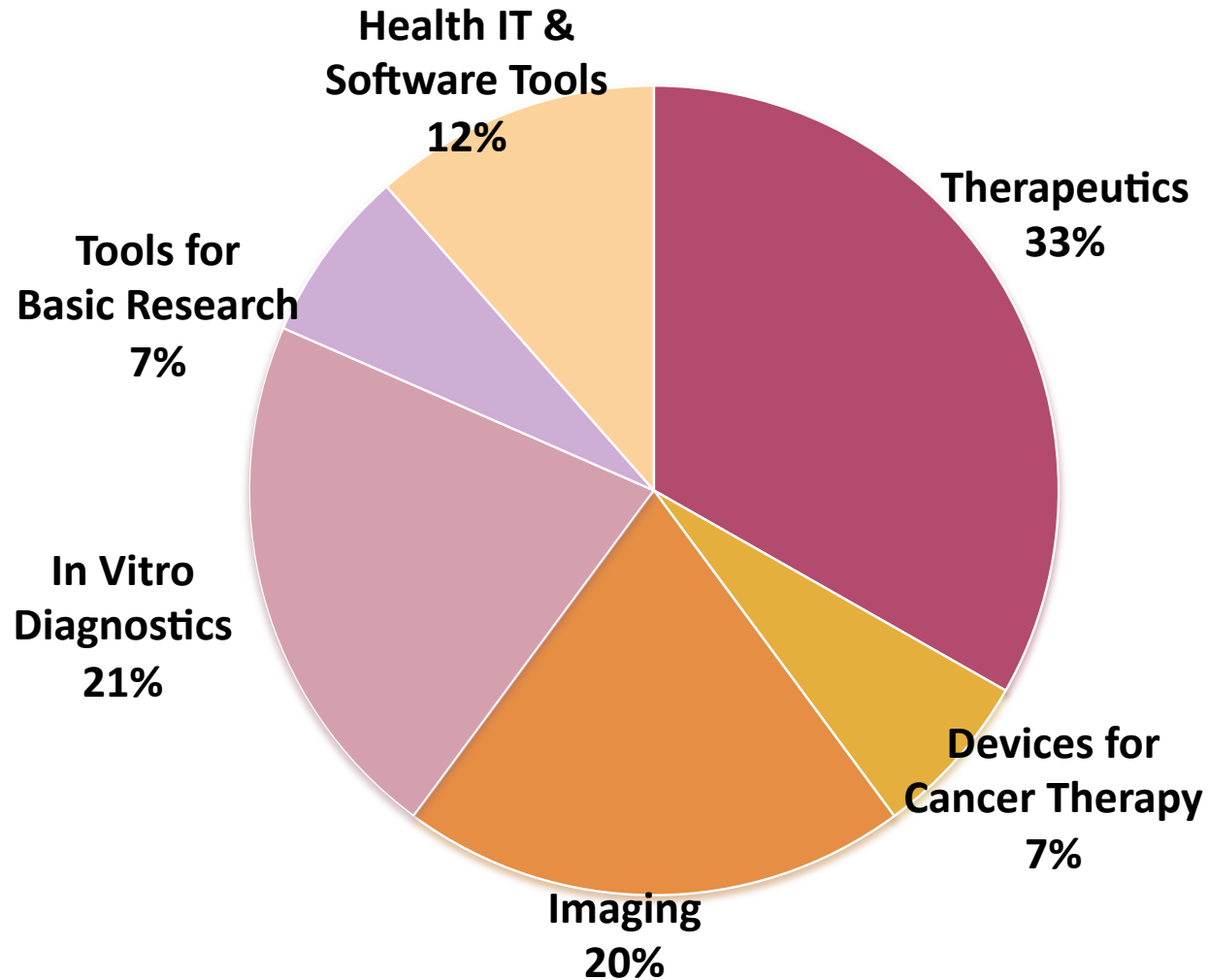


**Amir Rahbar, PhD, MBA**  
*Program Director*  
In-Vitro Diagnostics, Biologics, Therapeutics, Proteomics, SBIR Investor Forum



**Jennifer Shieh, PhD**  
*Program Director*  
Digital Health, Bioinformatics, Evaluation, SBIR Investor Forum, FRAC Workshop

# Pipeline of 400+ vetted projects



***Exclusive opportunity for some of the most promising NCI-funded companies to showcase their technologies***

**<http://sbir.cancer.gov/investorforum/>**



- In 2012, 18 top SBIR-funded companies presented
- Over 200 life science investors & leaders
- 150+ one-on-one meetings
- 2010 Investor Forum: 8 out of 14 presenting companies closed deals collectively valued at over \$230M



***Bringing together NCI SBIR/STTR  
awardees to move funded technologies  
from bench to bedside***

**<http://sbir.cancer.gov/FRACWorkshop>**

- May 7, 2013 at NCI Shady Grove
- Speakers from FDA, CMS, USPTO, and White House OSTP
- Panels on other sources of federal funding, resources & collaborative programs at NIH, and unique life science investment organizations
- One-on-one meetings with program directors and speakers

# Agenda



|                                                                                                                    |                |
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| Closing Remarks                                                                                                    | 4:25 pm        |

<http://sbir.cancer.gov/funding/contracts>

# What Does It Take to Get Awarded?

## *Tips on Submitting a Contract Proposal*





# The Contracts Proposal Process



**Must be received by  
November 25, 4:30 pm ET**

**August**



**Jan - Apr**



**June - July**



**September**



Solicitation  
Release

Build the  
Proposal

Submit the  
Proposal

Technical  
Review

Receive  
Notice to  
Offerors

Negotiation

Receive  
the Award

**YES**

**NO**

Receive  
Technical  
Evaluation  
Minutes

**Ask questions any time using the Q&A box**

# Read the Solicitation



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), THE  
NATIONAL INSTITUTES OF HEALTH (NIH) AND THE CENTERS FOR  
DISEASE CONTROL AND PREVENTION (CDC) SMALL BUSINESS  
INNOVATIVE RESEARCH (SBIR) PROGRAM**

**PROGRAM SOLICITATION PHS 2014-1**

**Closing Date: November 13, 2013, 4:30PM Eastern Time**

Participating HHS Components:

- The National Institutes of Health (NIH)
- The Centers for Disease Control and Prevention (CDC)

**IMPORTANT**

**Deadline for Receipt:** Proposals must be submitted by November 13, 2013, 4:30PM Eastern Time

Solicitation Changes:

As a result of program reauthorization, the solicitation has been EXTENSIVELY rewritten and follows the changes of the SBIR/STTR reauthorization. Please read the entire solicitation carefully prior to submitting your proposal.

Please go to <http://www.sbir.gov/about/sbir-policy-directive> to read the SBIR/STTR Policy Directive issued by the Small Business Administration.

<http://grants.nih.gov/grants/funding/SBIRContract/PHS2014-1.pdf>

**Read the Amendment too!**

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-013.html>

# Deciding to Submit a Proposal



- Your project fits the contract topic description
- You can achieve the specified milestones & deliverables
- Innovative solution to significant **unmet clinical need**
- Significant commercial potential
- Leverages company/founder expertise
- Need funding to produce **feasibility data**
- Need funding for **development**
- Start-up: Too early for private investment
- Established SBC: No resources to try new approach, but board supports SBIR

# When NOT to Submit a Proposal



- Chasing solicitations – “why not?”
- Chasing “cool” technologies
- Need cash urgently
  - SBIRs take 8-16 months or more to get and you must start with Phase I (~\$225K)
- Incremental upgrade: no change to clinical paradigm
- “Me too” product matching competitor’s capabilities
- Basic research still required to demonstrate commercial and clinical feasibility

# Key Tips for Submitting a Proposal



- Start when the solicitation is released
  - Read the solicitation!
- Take care of the administrative registrations
  - DUNS
  - SAM.gov
  - SBA Company Registry  
(<http://sbir.gov/registration>)

# Key Tips for Submitting a Proposal



- **Build the right team**
  - Partner to fill gaps
  - Get letters of support (not required but can be helpful)
- **Reviewers only see the proposal**
  - How does your proposal fit with the contract topic?
  - What is the problem you are uniquely able to solve?
  - Why is this approach innovative?
  - What is the potential for commercialization?
- **Run your own “peer review”**
  - Read your material critically as if you were the reviewer; ask collaborators to review the proposal

# Before You Write a Contract Proposal or Grant Application



- Review similar, currently funded NIH projects
  - NIH Project RePORTER, <http://projectreporter.nih.gov/>
- For contracts, send your questions to Elizabeth Shanahan, [eshanahan@mail.nih.gov](mailto:eshanahan@mail.nih.gov)
- For grants, contact NCI Program Director in advance (at least 1 month before due date!) to discuss your specific aims and receive feedback
  - [NCIsbir@mail.nih.gov](mailto:NCIsbir@mail.nih.gov)
  - [http://sbir.cancer.gov/contact\\_us.asp](http://sbir.cancer.gov/contact_us.asp)

# Search Previous Awards



<http://projectreporter.nih.gov>

**TEXT SEARCH**

Text Search (Logic):  Search in ? Limit Project search to Limit Publication search to

☒ And ☐ Or ☐ Advanced

☒ Projects ☐ Publications ☐ Projects & Publications

☐ Project Title ☐ Project Terms ☐ Project Abstracts

Start Year: 2012 End Year: 2013

**PROJECT DETAILS**

Project Number:  Format: 5R01CA012345-04 Use '%' for wildcard, e.g. %R21% [Enter multiple project numbers/application IDs](#)

OR

1  R01  CA  811099  01  A1S1

Project Start Date: >=  Format: mm/dd/yyyy

Project End Date: <=  Format: mm/dd/yyyy

Award Notice Date: >  Format: mm/dd/yyyy

Agency/Institute/Center:  SELECT ☒ Admin ☐ Funding

NIH Spending Category:  SELECT

Funding Mechanism:  CLOSE

☒ Check/Uncheck All

☒ Research Project Grants

☐ Non-SBIR/STTR

☒ SBIR/STTR

☐ Research Centers

☐ Other Research-Related

☐ Training, Individual

☐ Training, Institutional

☐ Construction Grants

☒ R and D Contracts

☐ Non-SBIR/STTR Contracts

☒ SBIR/STTR Contracts

☐ Interagency Agreements

☐ Intramural Research

☐ Other

SELECT RESET CLEAR

Award Type:  SELECT



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<http://sbir.cancer.gov/funding/contracts>

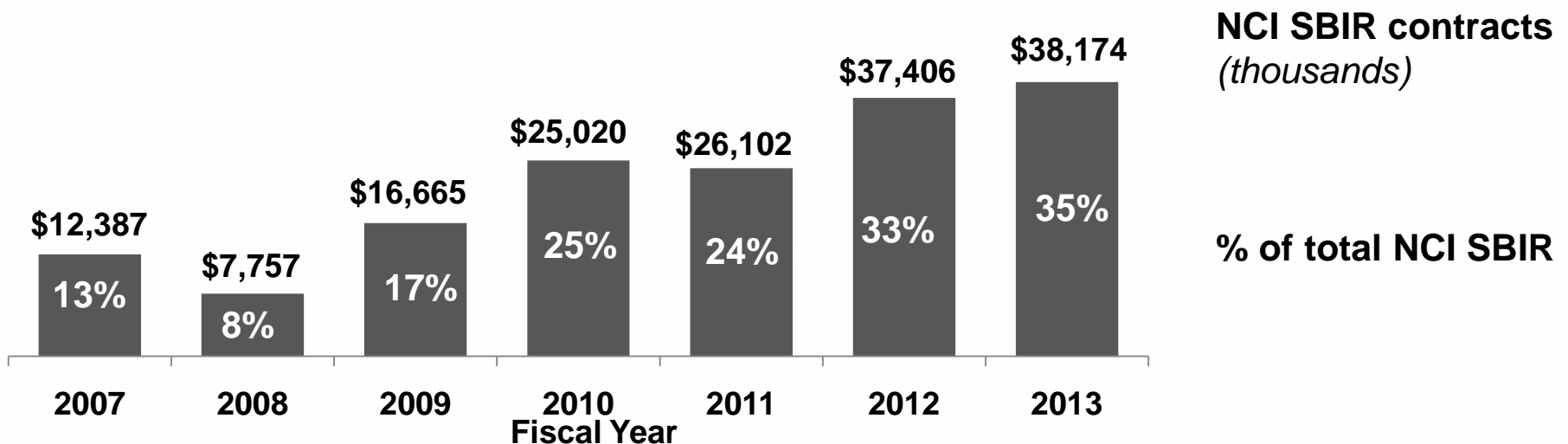
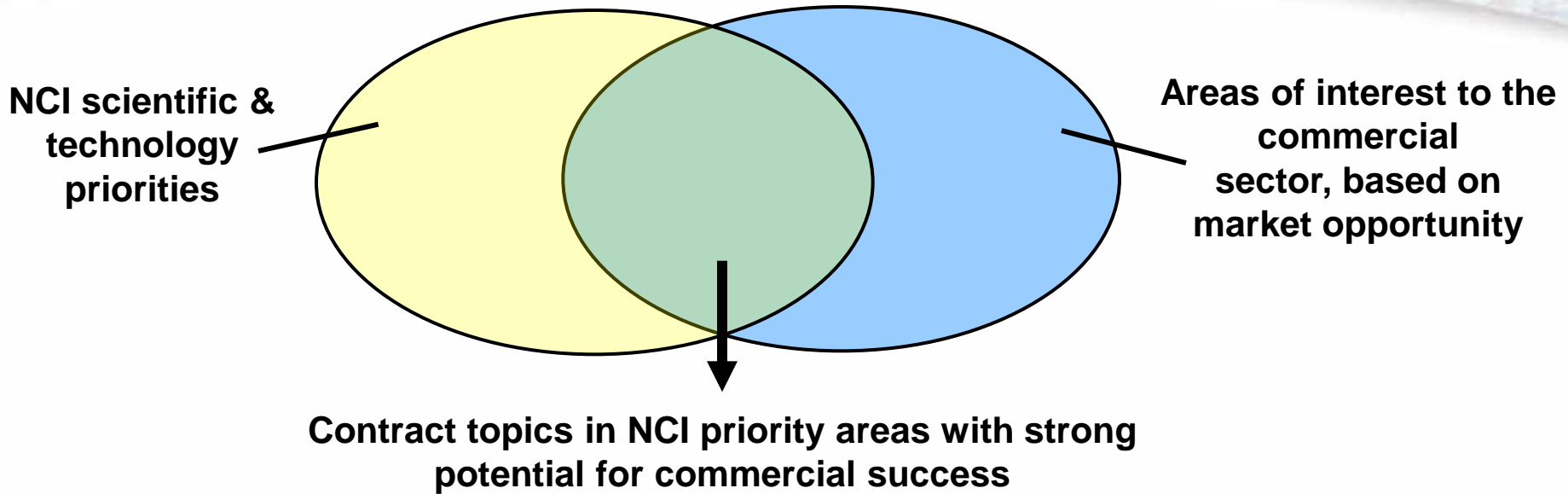
# The Contracts Process at NCI:

## How are SBIR Contracts Different from Grants?

<http://sbir.cancer.gov/funding/contracts>



# NCI SBIR Targeted Contract Solicitations



# SBIR Contracts vs. Grants



|                                                     | SBIR Grants                                              | SBIR Contracts                                                                         |
|-----------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------------------------------------|
| <b><i>Scope of the proposal</i></b>                 | Investigator-defined within the mission of NIH           | <b>Defined (narrowly) by the NIH</b>                                                   |
| <b><i>Questions during solicitation period?</i></b> | May speak with any Program Officer                       | <b><u>MUST</u></b> contact the contracting officer [eshanahan@mail.nih.gov]            |
| <b><i>Receipt Dates</i></b>                         | 3 times/year for Omnibus                                 | Only ONCE per year                                                                     |
| <b><i>Reporting</i></b>                             | One final report (Phase I);<br>Annual reports (Phase II) | Kickoff presentation, quarterly progress reports, final report, commercialization plan |
| <b><i>Set-aside funds for particular areas?</i></b> | No                                                       | Yes                                                                                    |
| <b><i>Program Staff Involvement</i></b>             | Low                                                      | High                                                                                   |

# SBIR Contracts vs. Grants



|                                 | SBIR Grants                                                                | SBIR Contracts                                                                                      |
|---------------------------------|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| <b><i>Peer Review Locus</i></b> | NIH Center for Scientific Review (CSR)                                     | <b>NCI Division of Extramural Activities (DEA)</b>                                                  |
| <b><i>Review Sections</i></b>   | Sections review applications for different programs in similar topic areas | Specific sections for each single topic                                                             |
| <b><i>Basis for Award</i></b>   | Peer review score<br>Program relevance & balance                           | Peer review score<br>Program relevance & balance<br>Negotiation of technical deliverables<br>Budget |
| <b><i>Fast Track</i></b>        | Ph I & II are considered as a single application with a single score       | Ph I & II are considered separate proposals; they are reviewed and scored independently             |

| Phase I Technical Evaluation Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                        | Weight |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| 1. The <b>soundness and technical merit</b> of the proposed approach based on: <ul style="list-style-type: none"><li>a. Clear measureable goals (milestones) that have a reasonable chance of meeting the topic objective in Phase I;</li><li>b. The approach is innovative and not routine,</li><li>c. Offeror's ability to implement technical approach</li></ul>                                                                                                          | 40%    |
| 2. The <b>qualifications of the proposed PDs/PIs</b>                                                                                                                                                                                                                                                                                                                                                                                                                         | 20%    |
| 3. The potential of the proposed research for <b>technological innovation</b> .                                                                                                                                                                                                                                                                                                                                                                                              | 15%    |
| 4. The potential of the proposed research for <b>commercial application</b> . The commercial potential of a proposal will be assessed using the following criteria: <ul style="list-style-type: none"><li>a. Whether the outcome of the proposed research activity will likely lead to a marketable product or process.</li><li>b. The offeror's discussion of the potential barriers to entry and the competitive market landscape as well as method to overcome.</li></ul> | 15%    |
| 5. The adequacy and suitability of the <b>facilities and research environment</b>                                                                                                                                                                                                                                                                                                                                                                                            | 10%    |

**See pg. 26 of PHS2014-1 for more details about the evaluation process**

# Contract Review Criteria



| For Fast-Track proposals:<br>Phase II Technical Evaluation Criteria                                                                                                                                                                                                                                                                                                                                                                                                                                     | Weight |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| 1. The <b>soundness and technical merit</b> of the proposed approach based on: <ul style="list-style-type: none"><li>a. Clear measureable goals (milestones) that have a reasonable chance of meeting the topic objective in Phase II;</li><li>b. The approach is innovative and not routine,</li><li>c. Offeror's ability to implement technical approach</li></ul>                                                                                                                                    | 30%    |
| 2. The potential of the proposed research for <b>commercial application</b> , as documented in the Commercialization Plan and evidenced by: <ul style="list-style-type: none"><li>a. Offeror's record of successfully commercializing prior SBIR/STTR or other research projects</li><li>b. Commitments of additional investment during Ph I &amp; Ph III from private sector or other non-SBIR funding sources</li><li>c. Other indicators of commercial potential for the proposed research</li></ul> | 30%    |
| 3. The <b>qualifications of the proposed PDs/PIs</b> , supporting staff and consultants.                                                                                                                                                                                                                                                                                                                                                                                                                | 25%    |
| 4. The adequacy and suitability of the <b>facilities and research environment</b>                                                                                                                                                                                                                                                                                                                                                                                                                       | 15%    |

**See pg. 26 of PHS2014-1 for more details about the evaluation process  
Amendment has updated weights**

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-013.html>



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| More Q&A                                                                                                           | 4:10 pm        |
| Closing Remarks                                                                                                    | 4:25 pm        |

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# Submit Your Questions



Please submit questions of a general nature, with no proprietary information.

We will not answer questions specific to your project in this webinar. Send your questions about:

**CONTRACTS** to Elizabeth

Shanahan, [eshanahan@mail.nih.gov](mailto:eshanahan@mail.nih.gov) or

**GRANTS** to [NCIsbir@mail.nih.gov](mailto:NCIsbir@mail.nih.gov)

The webinar slides, audio recording, and Q&A will be published to the website, <http://sbir.cancer.gov>

# Agenda



|                                                                                                                    |                |
|--------------------------------------------------------------------------------------------------------------------|----------------|
| <i>Welcome</i><br>Jennifer Shieh                                                                                   | 3:00 pm        |
| <i>Overview of the NCI SBIR/STTR Programs</i><br>Michael Weingarten                                                | 3:05 pm        |
| <i>What Does It Take to Get Awarded?</i><br><i>Tips on Submitting a Proposal</i><br>Michael Weingarten             | 3:15 pm        |
| <i>The Contracts Process at NCI:</i><br><i>How are SBIR Contracts Different from Grants?</i><br>Michael Weingarten | 3:30 pm        |
| Q&A                                                                                                                | 3:40 pm        |
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| More Q&A                                                                                                           | 4:10 pm        |
| Closing Remarks                                                                                                    | 4:25 pm        |

# FY 2014 NIH and CDC SBIR Contract Solicitation

<http://sbir.cancer.gov/funding/contracts>

*Presenters: Andrew Kurtz and Deepa Narayanan*



# Funding Opportunity Summary



PHS-2014-1 "HHS, NIH, and CDC SBIR Program Solicitation"

ONE proposal receipt date per year:

Published August 29, 2013; original deadline November 13

**EXTENDED**

**Receipt Date: November 25, 2013, 4:30 PM ET**

RFP can be found at:

<http://grants.nih.gov/grants/funding/SBIRContract/PHS2014-1.pdf>

Amendment: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-013.html>

More info about NCI's topic areas:

<http://sbir.cancer.gov/funding/contracts/>

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## Therapy & Diagnosis

- 326 Development of Novel Therapeutic Agents that Target **Cancer Stem Cells**
- 327 **Reformulation** of Failed Chemotherapeutic Drugs
- 331 Development of a Biosensor-Based Core Needle **Tumor Biopsy Device**
- 332 Development of **Radiation Modulators** for Use During Radiotherapy

## Advancing Cancer Research

- 328 Validation of 3D Human **Tissue Culture Systems** that Mimic the Tumor Microenvironment
- 329 **Proteomic** Analysis of Single Cells Isolated from Solid Tumors
- 330 Generation of Site-Specific **Phospho-Threonine Protein Standards** for Use in Cancer Assays

## Health IT

- 333 **Software Tools** for the Development of Environmental Measures Related to Cancer Health Behavior and Resources



# Topic 326: Development of Novel Therapeutic Agents that Target Cancer Stem Cells



**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 3 – 5

*Fast-Track proposals **not** accepted.*

**Goal:** Development of novel therapeutic agents that target cancer stem cells (CSCs), CSC-related biomarkers, or CSC pathways that affect fundamental processes associated with carcinogenesis, tumor progression, maintenance, recurrence or metastasis. Emphasis is placed on agents that target CSC self-renewal, regeneration, or differentiation processes.

## **Phase I Activities & Deliverables Include:**

- Demonstrate in vitro efficacy for the agent(s) that targets CSCs.
- Validate effect of the agent(s) on CSCs.
- Conduct structure-activity relationship (SAR) studies, medicinal chemistry, and/or lead antibody optimization.
- Perform animal toxicology and pharmacology studies as appropriate for the agent(s) selected for development.
- Develop a detailed experimental plan (to be pursued under a future SBIR Phase II award) necessary for filing an IND or an exploratory IND.

# Topic 327: Reformulation of Failed Chemotherapeutic Drugs



**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 2 – 4

*Fast-Track proposals accepted.*

**Goal:** Reformulation of small-molecule chemotherapeutic agents that have failed previously in pre-clinical development or in human clinical trials.

## **Approaches that are NOT accepted under this topic:**

- Chemical entities that have received FDA approval for any indication (cancer or otherwise).
- Chemically-modified, failed chemotherapeutic agents (i.e. traditional medicinal chemistry approaches are considered non-responsive).

## **Phase I Activities & Deliverables Include:**

- Identification of appropriate cancer indication(s) for proposed reformulated drug, and detailed experimental strategy
- Proof-of-concept attachment, encapsulation, or incorporation of the candidate chemotherapeutic agent to the delivery vehicle
- Proof-of-concept small animal studies demonstrating therapeutic efficacy and improved therapeutic index, bioavailability, etc. compared to use of free drug

# Topic 328: Validation of 3D Human Tissue Culture Systems that Mimic the Tumor Microenvironment



**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 5 – 7

*Fast-Track proposals accepted.*

**Goal:** Validation of 3D human tissue model culture systems that accurately mimic the tumor microenvironment using anti-cancer agents with known effects, to demonstrate the system's utility as a predictive tool, pre-clinical screening assay, and/or chemo-sensitivity assay.

## **Essential features include:**

- Multicellular architecture representing physiologically relevant characteristics
- Ability to examine multiple aspects of cancer, such as tumor growth, angiogenesis, etc
- Compatibility with high content screening platforms that include multiple molecular read-outs, such as genomic, proteomic, metabolomic, or epigenomic analyses.

## **Phase I Activities & Deliverables Include:**

- Validate a reproducible 3D culture that mimics the tumor microenvironment and appropriate pre-clinical or chemo-sensitivity assays to screen response to therapeutics
- Specify metrics used and criteria for prediction of clinical efficacy prior to demonstration of accurate prediction of clinical efficacy.
- Demonstrate accurate prediction of clinical efficacy or chemo-sensitivity in the culture system using at least one anti-cancer agent with known clinical profile.
- Benchmark performance against 2D and currently available 3D culture systems.

# Topic 329: Proteomic Analysis of Single Cells Isolated from Solid Tumors



**Budget:** Phase I \$160,000 for 9 months; Phase II \$1M for 2 years

**Number of Anticipated Awards:** 4

*Fast-Track proposals accepted.*

**Goal:** Advance field of single cell proteomics through optimization of single cell isolation from tumors, and the validation and benchmarking of proteomic analytical methods.

## **Phase I Activities & Deliverables Include:**

- Build cell isolation prototype
- Demonstrate proof-of-concept functionality using solid tumor clinical samples for proteomic analysis applications
- Establish a protocol to integrate single cell isolation technique into a proteomic platform, such as mass spectrometry

## **Phase II Activities & Deliverables Include:**

- Demonstrate medium to high-throughput single cell isolation capacity of the prototype and integrate all modules in the proteomic platform.
- Benchmark system by comparing and contrasting competitive advantage of prototype.

## Topic 330: Generation of Site-Specific Phospho-Threonine Protein Standards for Use in Cancer Assays



**Budget:** Phase I \$150,000 for 9 months; Phase II \$1M for 2 years

**Number of Anticipated Awards:** 3 – 5

*Fast-Track proposals accepted.*

**Goal:** Development of site-directed phospho-threonine protein synthesis technologies for the production of pThr protein/polypeptide standards.

### **Phase I Activities & Deliverables Include:**

- Develop proof-of-concept methodology to reliably produce threonine site-directed, high content (>50%), pThr-protein/polypeptide standards for at least 2 NCI-approved targets
- Demonstrate reproducibility & accuracy of methodology
- Demonstrate preliminary product stability

### **Phase II Activities & Deliverables Include:**

- Optimization of process to reproducibly generate quantitative, threonine site-specific phosphorylation for six NCI-approved targets
- Perform full validation of method

# Topic 331: Development of a Biosensor-Based Core Needle Tumor Biopsy Device



**Budget:** Phase I \$225,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 3 – 5

*Fast-Track proposals accepted.*

**Goal:** Advance development of biopsy needle-based biosensor technology that can determine regions of maximum tumor cellularity within a biopsy region.

## **Phase I Activities & Deliverables Include:**

- Manufacture and optimize needle-based biosensor device featuring:
  - Adaptability for use with existing imaging/ultrasound needle placement methods & needle biopsy procedures
  - Real-time signal generation distinguishing between tumor & non-tumor tissue
  - Demonstration of not damaging or changing tissue biology surrounding needle placement
- Show preliminary proof-of-concept of sensor-guided biopsy in relevant animal model

## **Phase II Activities & Deliverables Include:**

- Demonstrate feasibility of technique to complement current procedures
- Demonstrate performance of the device as designed and intended in relevant clinical veterinary models

# Topic 332: Development of Radiation Modulators for Use During Radiotherapy\*



**Budget:** Phase I \$200,000 for 9 months; Phase II \$1.5M for 2 years

**Number of Anticipated Awards:** 3 – 5

*Fast Track proposals accepted.*

**Goal:** Development of radiosensitizers, radioprotectants, or radiomitigators that decrease normal tissue injury and/or enhance tumor killing.

## **Phase I Activities & Deliverables Include:**

- *In vitro* testing
- Clonogenic survival studies
- Preliminary *in vivo* toxicity studies

## **Phase II Activities & Deliverables Include:**

- *In vivo* experiments
- PK/PD in rodent model
- GMP drug production/sourcing
- IND approval

Slight update in amendment, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-013.html>

\*Re-issue



## Topic 333: Software Tools for the Development of Environmental Measures Related to Cancer Health Behaviors and Resources



**Budget:** Phase I \$200,000 for 9 months; Phase II \$1M for 2 years

**Number of Anticipated Awards:** 2 – 3

*Fast Track proposals accepted.*

**Goal:** To support the development of an efficient, user-centered software tool that connects diverse data sources to enable the creation of metrics describing the environment related to health behaviors and services.

### **Phase I Activities & Deliverables Include:**

- Establish project team with broad expertise
- Prototype that facilitates use of existing APIs with salient data sources, allows import and export of data to and from existing tabular datasets, uses geographic identifiers compatible with major GIS software

### **Phase II Activities & Deliverables Include:**

- Beta-test and finalize:
  - methods for combining data into candidate metrics.
  - Develop, beta-test, and finalize data integration and visualization tools developed in Phase I
- Conduct usability testing

## Questions About Contracts?

**Ms. Elizabeth Shanahan**

[eshanahan@mail.nih.gov](mailto:eshanahan@mail.nih.gov)

240.276.5432

<http://sbir.cancer.gov/funding/contracts/>

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## NCI SBIR Development Center

[NCIsbir@mail.nih.gov](mailto:NCIsbir@mail.nih.gov)

Phone: 240.276.5300

<http://sbir.cancer.gov>

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# Thank You!

